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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

IV E17

April 24, 1974

NOTE FOR JOHN WHITNAH

With respect to the enclosed:

We propose a response to inquiry--something in the nature of a talking paper--rather than a public announcement. For that reason, we have no objection to editorial changes, rearrangement of paragraphs or the addition of material. In other words, there is no pride of authorship. In responding, we will talk from the material, not simply read it to the reporter.

But we do need the information necessary to handle press queries on this subject when the queries start arriving. For that reason, we would like restoration of the information which Kornfeld dropped. Whether or not it is restored, we would have to use it anyway if we are asked. The alternative would be to refuse to give it, and I don't think anyone wants to put the agency in that position.

After we get your blessing, I will show the General Manager and the Commissioners.

John A. Harris
John A. Harris, Director
Office of Information Services

Enclosure

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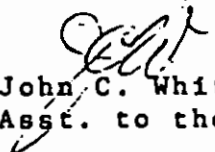
OFFICE OF THE GENERAL MANAGER

April 24, 1974

To: John A. Harris, Dir., OIS

Steve Greenleigh, OGC

Dr. Liverman would like your
review of the attached.


John C. Whitnah
Asst. to the AGMB

Office of the General Manager

GPO 808327

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WASHINGTON 20545

April 17, 1974

Carter - ok

WUB - ok

Mr Whitnah

Dr. Liverman:

The draft press release you wanted reviewed is altogether unacceptable. I have rewritten it, retaining the intent of the original version as much as possible.

Enclosed is a recently prepared "fact sheet" summarizing the plutonium studies in man. This goes into somewhat more detail than the press release. Additional supplemental information consists of articles by Durbin, Langham, Stone and Bair.

Dr. L. Kornfeld

Dr. L. Kornfeld

Enclosure:
As stated

Whitnah:

John this looks reasonably in order. Ple have Burr, Carter, review and then get to Greenleaf or Rowden for their perusal then to OIS → then to Chairman for herd review in case needed

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Response to Query on Plutonium Injection Study

The Atomic Energy Commission is conducting a staff inquiry into a study undertaken by the Manhattan Engineering District near the end of World War II to determine how plutonium, a man-made radioactive material, is deposited and excreted in the human body. The scientific community has been aware of this study for many years. An analysis of the findings may be found in the book, "Radiobiology of Plutonium," published in 1972 by the J. W. Press, University of Utah, Salt Lake City, Utah.

In the 1940's it was essential to establish realistic criteria for protecting the health of thousands of plutonium workers who were ~~exposed to~~ ^{working with} this hazardous material. For this purpose, accurate information on the retention and excretion of this radionuclide in man was required. A great deal had already been learned from experiments in animals, including the fact that the metabolic patterns of plutonium varied from one species to another. Thus, it was recognized that reliable information pertaining to man could be obtained only from persons who had received small but known amounts of this material and the decision was made to initiate studies designed to yield the needed data.

Between 1945 and 1947, 18 hospital patients were injected with varying amounts of plutonium. The subjects selected for the study generally were over 45 years old and suffered from chronic or malignant diseases such that survival for 10 years was highly improbable. All but one of the injections were given before the AEC was established in August 1946. Scientific studies were conducted for about five years after the injections. Much of what is known today about the retention of plutonium in man is based on data from these experiments.

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In 1972 and 1973, an investigator at an AEC contract facility arranged for follow-up studies on three surviving patients and on the body of one deceased patient. A series of papers describing the results of these recent studies will be presented at the International Congress for Radiation Research to be held in Seattle, Washington, in July 1974.

The inquiry now being conducted by AEC staff at the request of the five-member Commission, seeks to establish the circumstances under which this study was done, including whether any of the 18 patients or their next of kin were informed about the nature and purpose of the injections at the time they were given or when the recent follow-up studies were undertaken.

Policy guidelines for the conduct of medical experimentation on humans and the concept of informed consent were not clearly formulated until 1969. Subsequently, the AEC instituted the requirement that its contractors adhere to the 1969 guidelines of the National Institutes of Health. More recently, the revised policy of the Department of Health, Education and Welfare, as described in DHEW publication No. (NIH) 72-102, dated December 1, 1971, has been adopted.

The findings of the inquiry are to be reported to the Commission as soon as the investigation has been completed.

Plutonium Studies in Man.

The need to establish realistic criteria for limiting the exposure of plutonium workers to this hazardous material was foreseen in the early 1940's. An appreciation of the potential chronic toxicity of plutonium stemmed from studies in rodents designed to determine how plutonium body burdens might be estimated accurately from urinary excretion data. However, in view of the differences that had been observed in the metabolism of certain radionuclides in different animal species, it was recognized that reliable information pertaining to the deposition and excretion of plutonium in humans could only be obtained from persons to whom small but known amounts had been administered.

The decision to investigate the metabolism of plutonium in man was made by the Manhattan Engineering District (MED). Between 1945 and 1947, doses of plutonium in the range of 7 to 145 body burdens were administered to 18 hospital patients. Eleven of the patients were injected at Strong Memorial Hospital in Rochester, one at the Oak Ridge Hospital, three at Billings Hospital in Chicago, and three at the University of California Hospital in San Francisco. It is likely that all were injected intravenously except one patient with a malignant bone tumor in a leg; in the latter case the injection was made into a leg muscle four days before amputation. Only one of the 18 was injected after the AEC was established on August 1, 1946. According to an early document, the subjects chosen for the study generally were over 45 years of age and suffered from malignant or chronic disorders such that survival for ten years was highly improbable. In several instances, however, the medical conditions proved to be compatible with much longer survival than had been anticipated. Of the 18, one was lost to follow-up at an early date; six survived for more than ten years and of these, four are alive today.

The scientific studies were continued by the MED personnel and then by AEC contractors during the five year period after injection. In 1972, Dr. Patricia W. Durbin of Lawrence Berkeley Laboratory contributed a chapter to the monograph, "Radiobiology of Plutonium," in which she reviewed the essential clinical information on the patients and presented data of the completed scientific studies.

In December 1972, the accumulated records of the investigation, then in the possession of Dr. Durbin, were transferred to the Director, Center for Human Radiobiology (CHR) at Argonne National Laboratory (ANL). Subsequently, he arranged for clinical examinations and excreta collections for three surviving patients at Strong Memorial Hospital in Rochester. The specimens were analyzed for plutonium content at ANL and Los Alamos Scientific Laboratory. On one of these patients, a physical examination and radioactivity measurements were performed

at ANL in addition to the medical workup at Rochester. The recent examinations were performed between January and June 1973. In addition, the Director CHR obtained permission for the exhumation of the body of one injected patient. Studies on the remains have been carried out since the exhumation in September 1973.

For more than 25 years, estimates of body burdens of plutonium have been based on the early data collected from the injected patients. The recent information obtained from the survivors permits a more accurate construction of the excretion curve. Measurements of residual body content of plutonium and observations concerning its distribution within bone will become available from the exhumation study.

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